Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date: 06/12/2013

## **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Northwest	052051503	04/14/08	729	50(5)	33(688)	602.8	Metal working fluids (CIMSTAR 3800)
					Female		
Battelle Northwest	052051503	04/14/08	731	50(5)	35(700)	384.9	Metal working fluids (CIMSTAR 3800)

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female			
#All Organs: Benign Tumors										
•		32/50 (64%)				42/50 (84%)				
Overall Incidence	Total	32/50 (64%)	Mean 64%	SD 0%	Total	42/50 (84%)	Mean 84%	SD 0%		
#All Organs: Malignant Tumors										
		13/50 (26%)				11/50 (22%)				
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	11/50 (22%)	Mean 22%	SD 0%		
#All Organs: Malignant and Benign To	umors									
		37/50 (74%)				43/50 (86%)				
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	43/50 (86%)	Mean 86%	SD 0%		
#All Organs: Hemangioma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Hemangiosarcoma										
		3/50 (6%)				1/50 (2%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#All Organs: Hemangiosarcoma or He	emangioma									
		3/50 (6%)				1/50 (2%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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				Male				Female			
#All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated  0/50 (0%)  0/50 (0%)											
Overall Incidence	Total	0/50 (0%)	()	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Malignant Lymphoma: Hist	tiocytic, Lymp	hocytic, Mixed	, NOS, or	Undifferentiated Ce	II Type						
			(0%)				2/50 (4%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#All Organs: Mesothelioma: Benign, Ma	lignant, NOS	1/50	(2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	(,	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Mesothelioma: Malignant		1/50	(2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	(=75)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Osteoma		0/50	(00()				0/50 (00/)				
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Osteosarcoma											
• " " "	<b>T</b>		(2%)		05.00/	<b>-</b>	0/50 (0%)	<b>M</b> 00/	<b>OD</b> .00/		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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				Male			Female			
#All Organs: Osteosarcoma or Osteoma										
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		1/30 (2/8)					0/30 (0 %)			
*Adrenal Cortex: Adenoma										
			(4%)		05.00/		2/50 (4%)		00.00	
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Adrenal Cortex: Carcinoma										
		1/50	(2%)		05.00/		0/50 (0%)		00.00	
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benigr	1									
Overall Incidence	Total	4/50 4/50 (8%)	(8%)	Mean 8%	SD 0%	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Malign										
,		0/50	(0%)				1/49 (2%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	
*Adrenal Medulla: Pheochromocytoma: Benig		Malignant, NOS					2/49 (4%)			
Overall Incidence	Total	4/50 (8%)	, ,	Mean 8%	SD 0%	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female			
#Blood Vessel: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Bone Marrow: Hemangiosarcoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteoma	•••••	0/50 (09/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma or Osteoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Sarcoma		0/50 /00/				0/50 /00/			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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				Male			Female			
*Brain: Glioma										
Overall Incidence	Total	2/50 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Glioma Malignant		- /								
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Benig		0/50	(0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	(076)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Brain: Meningioma Malignant		1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	(= /0)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma: Benign, Malig	ınant, NOS	1/50	(20/)				0/50 (09/)			
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma, Glioma	a, or Astrocy	toma								
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female			
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Heart: Schwannoma Benign		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Leiomyosarcoma		0/50 (0%)		OD 00/	Total	0/50 (0%)	M 00/	00.00		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Unspec Leiomyosarcoma						0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 59

				Male				Female	
*Islets, Pancreatic: Adenoma									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 ( 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%
*Kidney: Pelvis and Transition	nal Epitheliu								
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma							1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Kidney: Renal Tubule: Lipoma									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 60

			Male				Female					
*Kidney: Renal Tubule: Liposarcoma												
-		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Liver: Hepatocellular Adenoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Liver: Hepatocellular Carcinoma	or Hepatocel					0/50 (0%)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Liver: Hepatocellular Carcinoma,	Hepatocellul	ar Adenoma, or Hepatob	lastoma			0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar Aden	oma	1/FO (20()				0/50 (09/)						
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar Carci	noma or Alve	eolar/Bronchiolar Adenor 1/50 (2%)	ma			0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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				Male			Female			
#Lymph Node, Mesenteric: Hemangioma										
		,	)%)		05 00/		0/50 (0%)		05 00/	
Overall Incidence	Total	0/50 (0%)	Mean	0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Hemangiosarcoma										
		,	5%)				1/50 (2%)			
Overall Incidence	Total	3/50 (6%)	Mean	6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Mammary Gland: Adenoma										
		,	)%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean		SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#Mammary Gland: Carcinoma		0/50 /0	2007				A/F0 (00/)			
Overall Incidence	Total	0/50 (0%)	0%) Mean		SD 0%	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma										
		0/50 (0	)%)				6/50 (12%)			
Overall Incidence	Total	0/50 (0%)	Mean	0%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%	
#Mammary Gland: Fibroadenoma										
	<b>.</b>	,	)%)	001	OD 00/	<b>.</b>	9/50 (18%)	100/	OD 00/	
Overall Incidence	Total	0/50 (0%)	Mean	υ%	SD 0%	Total	9/50 (18%)	Mean 18%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female						
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma												
		0/50 (0%)				11/50 (22%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	11/50 (22%)	Mean 22%	SD 0%				
#Mammary Gland: Fibroma, Fibroadenoma	, Carcinoma, or	Adenoma										
	, , .	0/50 (0%)				13/50 (26%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	13/50 (26%)	Mean 26%	SD 0%				
#Mesentery: Hemangiosarcoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
		, ,				, ,						
#Mesentery: Schwannoma Malignant		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Nose: Olfactory Neuroblastom	a											
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Oral Cavity (Oral Mucosa Squamous Cell Carcinor		nx, Tooth, Gingiva):										
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: Wistar Han

Species: RATS

#### **Toxicology Data Management System**

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Mean 0%

SD 0%

Report Date: 06/12/2013

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% **#Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% \*Ovary: **Granulosa Cell Tumor Benign** 1/50 (2%)Overall Incidence Total 1/50 (2%) Mean 2% SD 0% ..... \*Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/50 (0%) \*Ovarv: Granulosa Cell Tumor: Benign, Malignant, NOS 1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Sex Cord Stromal Tumor, Benign 0/50 (0%)

Total

0/50 (0%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female					
*Pancreas: Adenoma												
		1/50 (2%)				0/49 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%				
*Pancreas: Carcinoma or Adenoma												
		1/50 (2%)				0/49 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Distali Adenoma		eified Site:				25/50 /70%						
Overall Incidence	Total	16/49 (33%) 16/49 (32.65%)	Mean 32.65%	SD 0%	Total	35/50 (70%) 35/50 (70%)	Mean 70%	SD 0%				
		` ,				, ,						
*Pituitary Gland: Pars Distali Carcinoma or Adenoma	s or Unspec											
		16/49 (33%)				35/50 (70%)						
Overall Incidence	Total	16/49 (32.65%)	Mean 32.65%	SD 0%	Total	35/50 (70%)	Mean 70%	SD 0%				
*Pituitary Gland: Pars Interm												
		2/49 (4%)				1/50 (2%)						
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:											
		2/49 (4%)				1/50 (2%)						
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 65

			Male				Female	
*Prostate: Adenoma	Tara	1/50 (2%)	M 00/	OD 00/				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%				
*Prostate: Carcinoma or Adenoma		1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%				
*Salivary Glands: Myoepithelioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant						0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%				
#Skeletal Muscle: Sarcoma		0/50 /651				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overan incidence	างเลเ				rotai	0/50 (0%)		SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 66

			Male				Female					
#Skin: Basal Cell Adenoma  0/50 (0%)  0/50 (0%)												
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Adenoma or	Rasosquamous	Tumor Benjan				••••••						
Dasai Geli Adeliolila Gi	Dasosquamous	0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Adenoma, B		umor Benign, or Tricho				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Carcinoma		4/50 (00()				0/50 (00/)						
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skin:		•••••										
Basal Cell Carcinoma o	or Basosquamou	s Tumor (malignant or 1/50 (2%)	NOS)			0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous T	umor (benign, maligna	ant or								
		1/50 (2%)				0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han
Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male **Female** #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 2/50 0/50 (4%)2/50 (4%) Mean 0% Overall Incidence Total Mean 4% SD 0% Total 0/50 (0%) SD 0% #Skin: **Fibroma** 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 2/50 (4%)0/50 (0%)**Overall Incidence** Total 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) Mean 0% SD 0% ..... #Skin: **Fibrosarcoma** 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) SD 0% Mean 0% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) SD 0% Mean 0% ..... #Skin: Hamartoma (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		4/50 (00/)				0/50 (00/)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Neurofibrosarcoma or S	Schwannoma (m	alignant or NOS) 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neu		chwannoma (benign, ma 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page**: 69

			Male				Female				
#Skin: Schwannoma Malignant											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Carcinoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell C	Carcinoma, Basosquam	ous Tumor (malignar	nt or NOS),		0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papilloma o											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papilloma, l	Papilloma, S	-	na or Keratoacanthor	na							
		1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 70

				Male			Female					
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma  1/50 (2%)  0/50 (0%)  0/50 (0%)												
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Adenoma		0/50 //	(00/)				0/50 (00/)					
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Carcinoma or Adenoma			0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Spleen: Hemangiosarcoma			[0%]				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Stomach, Forestomach: Leiomyoma												
Overall Incidence	Total	1/50 (2%)	[2%]	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Stomach, Forestomach: Leiomyosarcoma		0/50 (	0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	(= : <del>=</del> /	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 71

				Male				Female				
#Stomach, Forestomach: Sarcoma												
		1/50	(2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Stomach, Forestomach: Squamous Cell Carcinoma							0/50 (00)					
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Stomach, Forestomach: Squamous Cell Carcinoma of Overall Incidence	or Papilloma	a Squamous 0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Stomach, Glandular: Leiomyosarcoma Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
Overall incidence		0/50 (0%)			3D 0%	TOTAL	1/50 (2%)	2%	3D 0%			
#Stomach, Glandular: Sarcoma												
		1/50	(2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Testes:												
Adenoma		2/50	(4%)									

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 72

			Male			Female					
*Thymus: Sarcoma											
		0/40 (0%)				0/48 (0%)					
Overall Incidence	Total	0/40 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%			
*Thymus: Thymoma Benign											
		1/40 (3%)				5/48 (10%)					
Overall Incidence	Total	1/40 (2.5%)	Mean 2.5%	SD 0%	Total	5/48 (10.42%)	Mean 10.42%	SD 0%			
*Thymus: Thymoma: Benign, Maligna	ant, NOS										
		1/40 (3%)				5/48 (10%)					
Overall Incidence	Total	1/40 (2.5%)	Mean 2.5%	SD 0%	Total	5/48 (10.42%)	Mean 10.42%	SD 0%			
*Thyroid Gland: C-Cell: Adenoma		7/50 (14%)				3/50 (6%)					
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%			
*Thyroid Gland: C-Cell: Carcinoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Thyroid Gland: C-Cell: Carcinoma or Adenoma											
		7/50 (14%)				3/50 (6%)					
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 73

				Male				Female			
*Thyroid Gland: Follicular Cell: Adenoma											
			(2%)				1/50 (2%)				
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Thyroid Gland: Follicular Cell: Carcinoma											
			(0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		4/50	(00()				0/50 (404)				
Overall Incidence	Tatal	1/50	(2%)	Mana 20/	CD 00/	Tatal	2/50 (4%)	Mana 40/	CD 00/		
Overall incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
*Urinary Bladder: Carcinoma or Papilloma		2/72	(00)				(201)				
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
		` '									
*Urinary Bladder: Papilloma											
			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Carcinoma											
							1/50 (2%)				
Overall Incidence						Total	1/50 (2%)	Mean 2%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 74

	Male		Female				
#Uterus: Polyp Stromal							
Overall Incidence		Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%		
#Uterus: Sarcoma Stromal							
Overall Incidence		Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
#Uterus: Sarcoma Stromal or Polyp Stromal							
Overall Incidence		Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%		
#Uterus: Schwannoma Malignant							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Squamous Cell Papilloma							
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Vagina: Leiomyoma			0/50 (0%)				
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar Han

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 75

			Male		Female			
#Vagina: Polyp								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied